EXHIBIT D

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Adam M. Slater

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Dear Mr. Slater,

This report sets forth my opinions with regard to the question of whether ingestion of NDMA and NDEA as a contaminant or impurity of valsartan (hereinafter "contaminated valsartan") can cause cancer in humans, and more particularly at the levels documented in the testing that has been performed. As set forth in more detail herein, it is my opinion to a reasonable degree of medical and scientific certainty that the levels of NDMA and NDEA documented in the contaminated valsartan at issue increase the risk that the people ingesting the contaminated valsartan will develop cancer, and that some number of those people likely already have and/or will in the future develop cancer as a result. This and any other opinions set forth herein are based on my education, training, and knowledge, medical and scientific literature, and review of documents in connection with this report. All opinions are held to a reasonable degree of medical and scientific certainty or greater. My discussion of the contaminated valsartan is focused primarily on NDMA studies and is phrased in terms of NDMA as that is the most commonly studied nitrosamine; however, the discussion applies to NDEA as well, which is considered to be even more potent than NDMA, unless otherwise indicated.

contributing factor in causing, gastric cancer. However, infection with *Helicobacter pylori* is a well-known and common cause of gastric cancer. (58) This is not to say that most patients with *Helicobacter pylori* get gastric cancer. In fact, the vast majority do not. There are several variables which determine whether a Helicobacter pylori infected patient gets gastric cancer, and NDMA consumption is likely one of them. (59) This is to say that "specificity" is a largely if not fully inapplicable criterion when considering multifactorial diseases. Rather, carcinogenic insults may be cumulative (e.g. alcohol abusers who also have chronic hepatitis c virus are more prone to liver cancer than patients with just alcohol abuse or chronic hepatitis c virus), thus the mechanism of NDMA causation of cancer, and the combination of animal and human data, make clear that NDMA can be a direct cause or contributor to cancer in humans. Of course, the Hill criteria, or "viewpoints," are not intended to be rigidly applied, and nor is it necessary for each factor to be satisfied in order to establish a causal association; thus, whether or not specificity is established is not determinative by any means. (1)

Manufacturers Testimony and Documents.

The manufacturers have also confirmed the causal relationship between the nitrosamines and cancer in humans. Min Li, Ph.D., testified that (1) the WHO 2002 article discussed above is scientifically reliable, (2) ZHP's own Deviation Investigation Reports recognize that NDMA is considered a probable human carcinogen, (3) due to the potent carcinogenicity of NDMA it would be unethical to knowingly give NDMA to humans, including at the levels seen in ZHP's valsartan API, (4) ZHP's consulting toxicologist Charles Wang, Ph.D. advised Min Li, Ph.D. that NDMA should actually be a Class 1 carcinogen, not a Class 2A, due to the established risk in experiments on rodents, and (5) Dr. Wang consulted a second toxicologist with special

expertise in the carcinogenicity issues and regulatory framework, on behalf of ZHP, and that toxicologist confirmed the strength of the evidence for human carcinogenicity. (Min Li Dep. Tr. 4/22/21, 657:18-662:10, 683:4-9, 685:11-687:4, 661:6-9, 551:15-552:16, 565:14-566:18, 573:7-574:9, 622:3-648:5). ZHP also stated in the Deviation Investigation Report for the TEA process that "NDEA is considered as a probable human carcinogen based on projection from the animal studies." ZHP cited to Pharmol. Ther., 1996, Vol. 71, Nos. 1/2, pp. 57-81 for this. ZHP also cited to Int. J. Biol. Sci. 2013, Vol. 9, No. 3, pp.237-245 for the observation that NDEA "is one of the most potent chemical hepatocarcinogens of this class, which can induce a variety of liver lesions in rodents." (PRINSTON0075850).

Bandaru Venkata Ramarao, Vice President of Quality Control for Hetero Unit 5 (the finished dose manufacturing division of Hetero), confirmed in his deposition that (1) NDMA is a probable human carcinogen, (2) NDMA can cause cancer, (3) NDMA increased the risk of cancer for those who took the pills, (4) NDMA does cause cancer in humans, (5) Hetero deemed the risk posed by the NDMA contamination to be at the highest level, and (6) it would never be acceptable for Hetero to knowingly sell valsartan contaminated at the levels established for its contaminated valsartan. (B.V. Ramarao Dep. Tr. 4/29/21, 259:20-268:4, 377:5-20, 4/30/21, 342:14-343:19).

Lance Molnar, Ph.D, Mylan's Senior Director, Global Pharmacology and Toxicology, testified with regard to the categorization of nitrosamines by the regulatory bodies as non-threshold, or in other words not subject to the presumed acceptable thresholds set forth in applicable guidelines by "the EMA, FDA, ICH … regulatory bodies in general" and that "non-threshold